

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s): **HILDEBRAND et al** Group Art Unit: **1616**
 Serial No.: **10/808,129** Examiner: **David Paul Stitzel, Esq.**
 Filed: **March 24, 2004** Docket No.: **134.02500101 (P-20904.00)**
 Title: **INTRATHECAL GABAPENTIN COMPOSITIONS**



Mail Stop Amendment
 Commissioner for Patents
 P.O. Box 1450
 Alexandria, VA 22313-1450

We are transmitting the following documents along with this Transmittal Sheet (which is submitted in triplicate):

An itemized return postcard.
 A Petition for Extension of Time for month(s) and a check in the amount of \$ for the required fee.
 An Information Disclosure Statement (2 pgs); 1449 forms (4 pgs); and copies of 39 documents cited on the 1449 forms.
 A request for continued examination (RCE) and a check in the amount of \$, for the required filing fee.
 An Appeal Brief and a check in the amount of \$, for the required Appeal Brief filing fee.
 A check in the amount of \$, for .
 A certified copy of a application, Serial No. , filed , the right of priority of which is claimed under 35 U.S.C. §119.
 Other:
 Amendment No Additional fee is required. The fee has been calculated as shown:

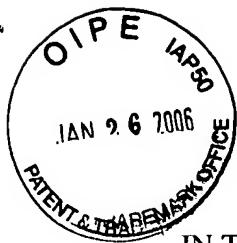
Fee Calculation for Claims Pending After Amendment					
	Pending Claims after Amendment (1)	Claims Paid for Earlier (2)	Number of Additional Claims (1-2)	Cost per Additional Claim	Additional Fees Required
Total Claims				x \$50 =	
Independent Claims				x \$200 =	
One or More New Multiple Dependent Claims Presented? If Yes, Add \$360 Here →					
Total Additional Claim Fees Required					

Please consider this a PETITION FOR EXTENSION OF TIME for a sufficient number of months to enter these papers and please charge any additional fees or credit overpayment to Deposit Account No. 13-4895. Triplicate copies of this sheet are enclosed.

CERTIFICATE UNDER 37 C.F.R. §1.8: The undersigned hereby certifies that this Transmittal Letter and the paper(s), as described hereinabove, are being deposited in the United States Postal Service, as first class mail, in an envelope addressed to: Mail Stop Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on this 29th day of January, 2006.

MUETING, RAASCH & GEBHARDT, P.A.
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PATENT
Docket No. 134.2500101 (P-20904.00)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

INFORMATION DISCLOSURE STATEMENT

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450
01/26/2006 HDEMESS1 00000061 134895 10808129

01/26/2006 HDEMESS1 00000061 134895 10808129

01 FC:1806 Sir: 180.00 DA

In compliance with the duty imposed by 37 C.F.R. § 1.56, and in accordance with C.F.R. §§ 1.97 *et. seq.*, the materials enclosed herewith are brought to the attention of the Examiner as possibly being of interest in connection with the above-identified patent application. Per M.P.E.P. §609, the information cited in the present Information Disclosure Statement shall not be construed to be an admission that the information is, or is considered to be, material to patentability. Consideration of each of the documents listed on the attached 1449 forms is respectfully requested. Pursuant to the provisions of M.P.E.P. §609, Applicant further requests that a copy of the 1449 forms, marked as being considered and initialed by the Examiner, be returned with the next Official Communication.

Since this Information Disclosure Statement is submitted after the receipt of an Office Action in the above-identified patent application, please charge the fee of \$180 under 37 C.F.R. §§1.97(c) and 1.17(p), or charge any additional fees, or credit any overpayment, to Deposit Account No. 13-4895.

Information Disclosure Statement

Applicant(s): HILDEBRAND et al.

Serial No.: 10/808,129

Confirmation No.: 4529

Filed: March 24, 2004

For: INTRATHECAL GABAPENTIN COMPOSITIONS

Page 2 of 2

The Examiner is invited to contact Applicants' Representatives at the below-listed telephone number if they can be of any assistance during prosecution of the present application.

CERTIFICATE UNDER 37 C.F.R. 1.8:

The undersigned hereby certifies that this paper is being deposited in the United States Postal Service, as first class mail, in an envelope addressed to: Mail Stop Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on this 24th day of January, 2006.


Kevin W. Raasch

January 24, 2006
Date

KWR/skd

Respectfully submitted

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Direct Dial 612/305-1218

INFORMATION DISCLOSURE STATEMENT 	Atty. Docket No.: 134.02500101 (P-20904.00)	Serial No.: 10/808,129
	Applicant(s): HILDEBRAND et al.	Confirmation No.: 4529
	Application Filing Date: March 24, 2004	Group: 1616
	Information Disclosure Statement mailed: January 24, 2006	

U.S. PATENT DOCUMENTS

Examiner Initial		Document Number	Date	Name	Class	Subclass	Filing Date If Appropriate
		5,713,923	02/03/98	Ward et al.			

FOREIGN PATENT DOCUMENTS

Examiner Initial		Document Number	Date	Country	Class	Subclass	Translation	
							Yes	No
		<i>None</i>						

OTHER DOCUMENTS (Including Authors, Title, Date, Pertinent Papers, etc.)

Examiner Initial	Copy Enclosed	Document Description
	✓	Ben-Menachem et al., "Selected CSF biochemistry and gabapentin concentrations in the CSF and plasma in patients with partial seizures after a single oral dose of gabapentin," <i>Epilepsy Res.</i> , 1992; 11(1):45-49.
	✓	Bennett et al., "Future Directions in the Management of Pain by Intradiscal Drug Delivery," <i>J. Pain Symptom Manage.</i> , 2000; 20(2):S44-S50.
	✓	Caraceni et al., "Gabapentin as an Adjuvant to Opioid Analgesia for Neuropathic Cancer Pain," <i>J. Pain Symptom Manage.</i> , 1999; 17(6):441-445.
	✓	Chen et al., "Synergistic Effect between Intrathecal Non-NMDA Antagonist and Gabapentin on Allodynia Induced by Spinal Nerve Ligation in Rats," <i>Anesthesiology</i> , 2000; 92(2):500-506.
	✓	Cheng et al., "Antialloodynic Effect of Intrathecal Gabapentin and Its Interaction with Clonidine in a Rat Model of Postoperative Pain," <i>Anesthesiology</i> , 2000; 92:1126-1131.
	✓	Cho et al., "The Effect of Intrathecal Gabapentin on Mechanical and Thermal Hyperalgesia in Neuropathic Rats Induced by Spinal Nerve Ligation," <i>J. Korean Med. Sci.</i> , 2002; 17:225-229.

EXAMINER	Date Considered

*Examiner: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

INFORMATION DISCLOSURE STATEMENT	Atty. Docket No.: 134.02500101 (P-20904.00)	Serial No.: 10/808,129
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	✓	"Clinical Trials: Brain Infusion of Muscimol to Treat Epilepsy," [online]. [retrieved on 2003-12-15]. Retrieved from the Internet:<URL: http://www.clinicaltrials.gov/ct/show/NCT00005925?order=1 >; 4 pgs.
	✓	Eckhardt et al., "Gabapentin Enhances the Analgesic Effect of Morphine in Healthy Volunteers," <i>Anesthesia & Analgesia</i> , 2000; 91:185-191.
	✓	Field et al., "Gabapentin and pregabalin, but not morphine and amitriptyline, block both static and dynamic components of mechanical allodynia induced by streptozocin in the rat," <i>Pain</i> , 1999; 80(1-2):391-398.
	✓	Field et al., "Gabapentin (neurontin) and S-(+)-3-isobutylgaba represent a novel class of selective antihyperalgesic agents," <i>Br. J. Pharmacol.</i> , 1997; 121:1513-1522.
	✓	Goa et al., "Gabapentin. A Review of its Pharmacological Properties and Clinical Potential in Epilepsy," <i>Drugs</i> , 1993; 46(3):409-427.
	✓	Grabow et al., "Gabapentin Produces Dose-Dependent Antinociception in the Orofacial Formalin Test in the Rat," <i>Reg. Anesth. Pain Med.</i> , 2002; 27(3):277-283.
	✓	Hammond et al., "Pharmacological and Neuroanatomical Studies of the Antinociceptive Effects of Intrathecally Administered Gabapentin," <i>Masui</i> , 1998; 47 Suppl.:S229-S330.
	✓	Hunter et al., "The effect of novel anti-epileptic drugs in rat experimental models of acute and chronic pain," <i>Eur. J. Pharmacol.</i> , 1997; 324:153-160.
	✓	Hwang et al., "Effect of Subarachnoid Gabapentin on Tactile-Evoked Allodynia in a Surgically Induced Neuropathic Pain Model in the Rat," <i>Reg. Anesth.</i> , 1997; 22(3):249-256.
	✓	Jun et al., "The Effect of Intrathecal Gabapentin and 3-Isobutyl γ -Aminobutyric Acid on the Hyperalgesia Observed After Thermal Injury in the Rat," <i>Anesth. Analg.</i> , 1998; 86:348-354.
	✓	Kaneko et al., "Intrathecally Administered Gabapentin Inhibits Formalin-Evoked Nociception and the Expression of Fos-Like Immunoreactivity in the Spinal Cord of the Rat," <i>J. Pharmacol., Exp. Ther.</i> , 2000; 292(2):743-751.

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	✓	Laughlin et al., "Comparison of Antiepileptic Drugs Tiagabine, Lamotrigine, and Gabapentin in Mouse Models of Acute, Prolonged, and Chronic Nociception," <i>J. Pharmacol. Exp. Ther.</i> , 2002; 302(3):1168-1175.
	✓	Lu et al., "Gabapentin Attenuates Nociceptive Behaviors in an Acute Arthritis Model in Rats," <i>J. Pharmacol. Exp. Ther.</i> , 1999; 290(1):214-219.
	✓	McLeane, "Gabapentin reduces chronic benign nociceptive pain: a double-blind, placebo-controlled cross-over study," <i>The Pain Clinic</i> , 2000; 12(2):81-85.
	✓	Mellick et al., "Gabapentin in the Management of Reflex Sympathetic Dystrophy," <i>J. Pain Symptom Manage.</i> , 1995; 10(4):265-266.
	✓	Morello et al., "Randomized Double-blind Study Comparing the Efficacy of Gabapentin with Amitriptyline on Diabetic Peripheral Neuropathy Pain," <i>Archives of Internal Medicine</i> , 1999; 159:1931-1937.
	✓	Orza et al., "Neuropathic pain: Review of mechanisms and pharmacologic management," <i>NeuroRehabilitation</i> , 2000; 14:15-23.
	✓	Pandey et al., "Gabapentin for the Treatment of Pain in Guillain-Barré Syndrome: A Double-Blinded, Placebo-Controlled, Crossover Study," <i>Anesthesia & Analgesia</i> , 2002; 95: 1719-1723.
	✓	Partridge et al., "Characterization of the Effects of Gabapentin and 3-Isobutyl- γ -Aminobutyric Acid on Substance P-induced Thermal Hyperalgesia," <i>Anesthesiology</i> , 1998; 88:196-205.
	✓	Rice et al., "Gabapentin in postherpetic neuralgia: a randomised, double blind, placebo controlled study," <i>Pain</i> , 2001; 94:215-224.
	✓	Rosenberg et al., "The Effect of Gabapentin on Neuropathic Pain," <i>Clin. J. Pain.</i> , 1997; 13(3):251-255.
	✓	Rowbotham et al., "Gabapentin for the Treatment of Postherpetic Neuralgia: A Randomized Controlled Trial," <i>JAMA</i> , 1998; 280(21):1837-1842.
	✓	Serpell et al., "Gabapentin in neuropathic pain syndromes: a randomised, double-blind, placebo-controlled trial," <i>Pain</i> , 2002; 99(3):557-566.
	✓	Shimoyama et al., "Gabapentin enhances the antinociceptive effects of spinal morphine in the rat tail-flick test," <i>Pain</i> , 1997; 72:375-382.

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	✓	Shimoyama et al., "Spinal gabapentin is antinociceptive in the rat formalin test," <i>Neurosc. Lett.</i> , 1997; 222:65-67.
	✓	Suman-Chauhan et al. "Characterisation of [³ H]gabapentin binding to a novel site in rat brain: homogenate binding studies," <i>Eur. J. Pharmacol.</i> , 1993; 244(3):293-301.
	✓	Taylor et al., "A summary of mechanistic hypothesis of gabapentin pharmacology," <i>Epilepsy Res.</i> , 1998; 29:233-249.
	✓	Welty et al., "Gabapentin anticonvulsant action in rats: disequilibrium with peak drug concentrations in plasma and brain microdialysate," <i>Epilepsy Res.</i> , 1993; 16:175-181.
	✓	Yoon et al., "Characteristic of Interactions Between Intrathecal Gabapentin and Either Clonidine or Neostigmine in the Formalin Test," <i>Anesth. Analg.</i> , 2004; 98:1374-1379.
	✓	Yoon et al., "The Effect of Intrathecal Gabapentin on Pain Behavior and Hemodynamics on the Formalin Test in the Rat," <i>Anesth. Analg.</i> , 1999; 89:434-439.
	✓	Yoon et al., "Spinal Gabapentin and Antinociception: Mechanisms of Action," <i>J. Korean Med. Sci.</i> , 2003; 18:255-261.
	✓	Zahn et al., "Effect of Systemic and Intrathecal Morphine in a Rat Model of Postoperative Pain," <i>Anesthesiology</i> , 1997; 86(5):1066-1077 [online]. [retrieved on 2003-03-31]. Retrieved from the Internet:<URL: http://ipsapp002.lwwonline.com/content/getfile/3941/89/10/fulltext.htm >; 13 pgs.
	✓	Zour et al., "Stability Studies of Gabapentin in Aqueous Solutions," <i>Pharm. Res.</i> , 1992; 9(5):595-600.

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